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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,672	10/10/2000	Yasir Skeiky	014058-009041US	2671

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/688,672

Examiner

Rodney P. Swartz, Ph.D.

Applicant(s)

SKEIKY ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16July2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 and 105-115 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 and 105-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicants' Response to Restriction, received 16 July 2002, paper #7, is acknowledged.

Claims 29-104 have been canceled without prejudice. Claim 25 has been amended.

2. Applicants elect, with traverse, Invention I, claims 1-28, 105-115, drawn to amino acid antigens, classified in class 424, subclass 248.1.

Applicants' traversal is on the grounds that examining Inventions I-V together would not place an undue burden on the Examiner.

This is not found persuasive because for the reasons put forth in the original restriction requirement, i.e., the inventions are distinct for the reasons given, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

In response to the Election of Species Requirement, applicants elect antigen 85 complex and 3D-MPL.

3. Applicants' notice to Comply with Sequence Requirement, received 4 February 2003, is acknowledged and entered.

4. Claims 1-28 and 105-115 are pending and under consideration.

Drawings

5. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

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Specification

6. The disclosure is objected to because of the following informalities:
- a) page 1, lines 4-11, the status of each of the U.S. Pat. applications should be indicated, Appropriate correction is required.

Claim Objections

7. Claim 18 is objected to because of the following informality: line 3, "immungenic" should be "immunogenic". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
10. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The instant claims are drawn to pharmaceutical compositions comprising an Mtb antigen fusion polypeptide.

M.P.E.P. §2164.01(c), paragraph 3, recites:

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *in re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceuticals"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease"

While the definition of "pharmaceutical" is broad, it is not so broad to cover **any** use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant application, there are no examples of administration of the composition to subjects, merely the production *in vitro* of the constructs. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in a subject to which the substance is administered.

11. Claims 7-28 and 109-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are drawn to "an HTCC#1 antigen" or "a" full-length HTCC#1 antigen. However, the specification appears to teach only one "HTCC#1" which is SEQ ID NO:14, encoded by SEQ ID NO:13. Thus, it is unclear what is being claimed.

Also, the designations HTCC#1(184-392) and HTCC#1(1-129) are unclear. It would be better to list the proteins by sequence number, i.e., amino residues 184-192 of SEQ ID NO:14.

12. Claims 1-28 and 105-115 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antigens from *M. tuberculosis*, does not reasonably provide enablement for antigens from all other species of the tuberculosis complex. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to polypeptides obtained from *M. tuberculosis* or fragments thereof from a *Mycobacterium* species of the tuberculosis complex. However, the specification provides only examples of polypeptides obtained from *M. tuberculosis*. Thus, the instant claims constitute merely an invitation to experiment without a reasonable expectation of success concerning fragments of polypeptides from other species of the tuberculosis complex.

Conclusion

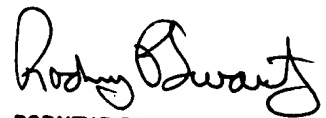
13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

A handwritten signature in black ink, appearing to read "Rodney Swartz".

RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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April 21, 2003